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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/252,322 02/18/99 CAMPBELL C MP/87C

QM12/1124

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EXAMINER

CHENEY, K

ART UNIT

PAPER NUMBER

3762

7

DATE MAILED:

11/24/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/252,322

Applicant(s)
Campbell et al

Examiner
Kelly M. Cheney

Group Art Unit
3762



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-69 is/are pending in the application.

Of the above, claim(s) 63-69 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-13 and 15-62 is/are rejected.

☒ Claim(s) 14 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2,4,6

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-62, 67, 68, drawn to the catheter balloon, classified in class 604, subclass 96.
 - II. Claims 63-66, drawn to balloon cover, classified in class 604, subclass 96.
 - III. Claim 69, drawn to the method of making a balloon, classified in class 604, subclass 271.
2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention I has separate utility such as drug delivery . See MPEP § 806.05(d).
3. Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the process can be used to make a stent .

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4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

5. Upon election of Group I, an election of species is required: Species A: Figs. 8-8A (claims 67-68) or Species B: Figs 10A-12C (claims 1-62). Upon election of Group II, an election of species is required: Species A: Figs 3A-3B, Species B: 4A-5B, or Species C: 6A-6C.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

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examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. During a telephone conversation with Wayne House on November 16, 1999 a provisional election was made without traverse to prosecute the invention of I, species B: claims 1-62.

Affirmation of this election must be made by applicant in replying to this Office action.

Claims 63-69 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-13, 15-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamilton in view of Ravenscroft et al. Hamilton discloses a multiple layer balloon comprising

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a thermoplastic elastomer in combination with a non-compliant structural polymeric material (2:28-30), having opposing ends bonded to the catheter (9:25-28) wherein the length of the balloon varies less than about 10 percent between when the balloon is in the deflated state and when the balloon is inflated and having a substantially circular cross section during inflation and deflation (Figs 1-2d). Ravenscroft et al teaches that Teflon, which is polytetrafluoroethylene, is a non-elastic material (5:63-64) and that PTFE, in the form of a strip (18), can be helically wrapped around a balloon (5:2-4 & Figs. 5-5B). It is well known in the art that PTFE is a porous material as stated in Abiuso et al (2:12-16). Therefore it would have been obvious to one of ordinary skill at the time of the applicant's invention to use PTFE as taught by Ravenscroft for the non-compliant material in Hamilton's balloon when a porous material is desired, especially when the balloon is to have a helically wrapped outer layer. Hamilton further disclose a balloon wherein the non-compliant material is adhered between two layers of the elastomer material (7:18-36 & Fig. 2c) which would inherently make the non-compliant material liquid-tight in that both sides of the non-compliant material would be sealed to the elastomer. It is well known in the art that balloon catheters are configured for stent and graft delivery. It is well known in the art that balloon burst pressures vary widely between balloon materials wherein non-compliant materials can often be rated to 16 atm or higher and compliant materials have lower rated pressure of 10 atm or higher. It would be obvious to one of ordinary skill in the art at the time of the applicant's invention that a balloon made of both compliant and non-compliant materials would have higher burst pressures than balloons made only of compliant materials and therefore would have burst pressure of at

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least 10 atm. It would be inherently obvious that balloons made of the materials of the applicant's invention would exhibit the same properties as the applicant's balloon and therefore, would have the same burst pressures and compaction ratios as the applicant's balloon.

Allowable Subject Matter

10. Claim 14 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to the applicant's disclosure. Hamilton (5797877), Wang et al (5951941), Wang et al (5512051), Wang et (5366442) and Green (5807327) disclose devices that are analogous to the applicant's invention.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kelly M. Cheney whose telephone number is (703) 306-5444.


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RONALD STRIGHT
PRIMARY EXAMINER

kmc



November 22, 1999